

EXHIBIT B

JONES DAY

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November 21, 2007

VIA EMAIL

Gejaa Gobena, Esq.
Civil Division
Commercial Litigation Branch
P.O. Box 261
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Washington, D.C. 20044

Re: *United States ex rel. Ven-A-Care of the Florida Keys v. Abbott Laboratories, Inc.*

Dear Gejaa:

Under Paragraph 13 of Case Management Order 29, please provide dates and witnesses on the following topics:

Interpretation of AWP

1. The authorship, utilization, reliance upon, accuracy of content, and distribution of all regulations, statutes, and guidance concerning payment for the Subject Drugs or claims at issue in this case.

2. CMS's contemporaneous position during 1991-2003 concerning the meaning of AWP in any relevant Medicare or Medicaid statute or regulation, and the manner in which CMS and its carriers interpreted or implemented AWP in accordance with that position, including but not limited to:

- (a) how CMS, its employees, agents, or carriers interpreted and applied the term "AWP" or "national average wholesale price" as used in 42 C.F.R. 405.517;
- (b) how CMS, its employees, agents, or carriers interpreted and applied the term "AWP" or "Average Wholesale Price" as used in Section 4556 of the Balanced Budget Act of 1997, 42 U.S.C. § 1395u;
- (c) whether CMS, its employees, agents, or carriers believed that "AWP is used to refer to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail customer who then administers it to a patient" (First Amended Complaint ¶ 41);

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- (d) whether CMS, its employees, agents, or carriers believed that “[t]he general concept that the AWP refers to the price at which a pharmaceutical firm or wholesaler sells a drug to its customers is commonly understood in the industry” (United States’ Objections and Responses to Defendant Abbott’s First Set of Interrogatories at 35 (12/4/2006));

3. The manner in which CMS, its employees, agents, or carriers have interpreted or implemented the term “Average Wholesale Price” or “AWP” since the passage of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (Pub. L. 108-173).

4. All facts or information related to CMS’s decision, as explained in Program Memorandum Transmittal AB-00-86 (September 8, 2000), to instruct Medicare carriers to consider AWP data generated by DOJ and NAMFCU as an alternative source of pricing information when determining payment for prescription drugs, and any facts or information related to CMS’s subsequent decision to withdraw the instructions issued in that Program Memorandum.

5. All facts or information sufficient to explain why CMS chose to include certain drugs but not others in the list appended to Program Memorandum Transmittal AB-00-86 (September 8, 2000).

6. The identity of any person at any time who believed that “AWP is used to refer to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail Customer who then administers it to a patient” (First Am. Compl. ¶41) or that AWP data “published in Red Book and other national drug listings generally represented a comprehensive source and indicia of market prices” (Brief of United States as Amicus Curiae (Sept. 15, 2006, MDL 1456)).

Continued Use of AWP

7. What steps CMS, its employees, agents, or carriers or any state Medicaid Program took upon learning of the Ven-A-Care *qui tam* complaints, the article published in *Barron’s* magazine entitled “Hooked on Drugs” (June 10, 1996), or any other communication advising them that AWP for the Subject Drugs exceeded the acquisition costs for those drugs.

8. Why CMS, its employees, agents, and carriers, and various state Medicaid programs continued to pay for drugs based on published AWP even when presented with evidence that AWP did not represent the price at which physicians and pharmacists purchased drugs, including whether the decision to pay for drugs based on AWP in Medicare or any state Medicaid program was affected in any way by

- (a) political negotiations;

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- (b) concern about adversely affecting access to care for Medicare and Medicaid beneficiaries; or
- (c) a deliberate effort to “cross subsidize” physicians and pharmacists for inadequate dispensing fees or inadequate payments for services rendered incident to administering infusion or injection drugs.

9. What the Medicare program or any state Medicaid program would have paid for the Subject Drugs had they had actual knowledge of the prices at which physicians and other customers purchased the Subject Drugs.

10. Any communications by CMS, its employees, agents, or carriers, DOJ, or any state Medicaid program to any compendia seeking to prevent, discourage, or alter in any way the publication of AWP data.

Legislation and Rulemaking

11. All communications during 1991-2003 between CMS and third parties, including but not limited to Congress (whether legislators, staff, or investigators), states, plaintiffs in drug pricing lawsuits, drug manufacturers, trade or industry groups, consultants, lobbying firms, patients’ rights groups, law firms, or any other non-governmental organizations concerning drug pricing, reimbursement, spread, the meaning of AWP, the relationship of AWP to acquisition costs, alternatives to AWP, or policy reasons to pay based on AWP rather than other methodologies.

12. All lobbying efforts by CMS, its employees, agents, or carriers, or by any state concerning Medicare or Medicaid (federal or state) drug reimbursement issues, including but not limited to lobbying and advocacy in connection with the drug payment provision of:

- (a) CMS’s Proposed Rule published at 56 Fed. Reg. 25792 (June 5, 1991) relating to payment for drugs under Medicare Part B;
- (b) the final version of the regulation relating to payment for drugs under Medicare Part B, published at 56 Fed. Reg. 59502 (Nov. 25, 1991);
- (c) the Medicare and Medicaid Beneficiary Protection Act of 1997, H.R. 2632, 105th Cong. § 206 (1997);
- (d) the Balanced Budget Act of 1997, Pub. L. 105-33, 111 Stat. 462-463;
- (e) CMS’s Proposed Rule published at 63 Fed. Reg. 30818, 30846 (June 5, 1998);

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- (f) CMS's Program Memorandum Transmittal AB-00-86 (September 8, 2000);
- (g) CMS's Proposed Rule at 68 Fed. Reg. 50428, at 50432-33 (August 20, 2003);
- (h) the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066, at § 2238 (amending 42 U.S.C. § 1395w-3) (2003); and
- (i) any other proposed or contemplated federal statute or regulation that would have established payment for prescription drugs under Medicare or Medicaid at the actual acquisition cost incurred by physicians or pharmacists in providing drugs to beneficiaries.

13. All facts related to CMS's decision in the final regulation, published at 56 Fed. Reg. 59502 (Nov. 25, 1991), to pay for prescription drugs under the Medicare program at 100% of AWP, rather than 85% of AWP as initially outlined in the Proposed Rule, published at 56 Fed. Reg. 25792 (June 5, 1991).

Medicaid

14. How CMS, its employees, agents, or carriers defined and implemented "estimated acquisition costs" during 1991-2003, and whether CMS and/or its employees, agents, and carriers believed that the formulae contained in each state plan would result in payment for drugs at the actual estimated acquisition costs of those drugs.

15. CMS's reasons for, and the drafting, editing, review, authorizing, and finalizing of the CMS Decision Memorandum entitled, "Review of State Plan Amendments," which was produced by the Government at HHC004-0188 to HHC004-0190 and marked as Abbott Deposition Exhibit 328.

16. Any and all efforts by CMS to establish a Federal Upper Limit for any of the Subject Drugs or Subject J-Codes during the Relevant Claim Period, as authorized by 42 C.F.R. § 447.332, and CMS's reasons for any decision or policy not to establish a FUL for the Subject Drugs and other injectables.

17. Any and all efforts by CMS to disapprove state Medicaid plan amendments that based payment for drugs on AWP for any of the Subject Drugs or Subject J-Codes during the Relevant Claim Period, and CMS's reasons for any decision or policy not to use its authority to disapprove state Medicaid plan amendments that paid for drugs based on AWP or any formula that did not result in an accurate estimate of acquisition costs.

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18. The frequency and manner in which each State Medicaid agency made findings and assurances to CMS during 1991-2003, as required by 42 C.F.R. § 447.333, that “[i]n the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.331 of this subpart,” as well as all communications between CMS and State Medicaid agencies regarding these findings and assurances, all related guidance or interpretations provided by CMS, all efforts by CMS during 1991-2003 to request and/or evaluate any “data, mathematical or statistical computations, comparisons, and any other pertinent records to support [the State Medicaid agencies’] findings and assurances” (§ 447.333(c)), or CMS’s reasons for any decision not to require states to make such findings and assurances. With respect to multiple source drugs for which CMS did not establish an upper limit under § 447.332, this topic includes the frequency and manner in which each State Medicaid agency made annual findings and assurances to CMS that “[i]n the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.331 of this subpart.” 42 C.F.R. § 447.333(b).

Abbott’s Conduct

19. Whether and to what extent CMS, its employees, agents, or carriers, or any state Medicaid program were aware between 1991 and 2003 of the market prices for the Subject Drugs and that Abbott was allegedly “marketing the spread.”

20. Any guidance, instruction, or requests communicated by CMS, its employees or agents, DOJ, or any state Medicaid program to Abbott regarding how to establish published and list prices.

21. Any guidance, instruction, or requests communicated by CMS, its employees or agents, DOJ, or any state Medicaid program to Abbott regarding marketing the spread.

Preservation of Evidence

22. All efforts taken to preserve evidence in response to the March 17, 2000 request made by various pharmaceutical manufacturers that the government not destroy evidence supporting those manufacturers’ defenses in this case. *See* Ex. E to Abbott’s Motion For a Preservation Order and Affidavit Regarding Spoliation Issues (Sept. 13, 2007).

23. The United States’ responses to subpoenas issued by defendants in the Lupron MDL and the AWP MDL to the HHS, including:

- (a) the policies, directives, instructions, and procedures and practices relating to the search for and collection of responsive documents;

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- (b) the scope of the search performed (including the United States' understanding and implementation of any agreements reached with defendants limiting the scope of production);
- (c) an identification of the individual employees, files, computers, locations, and divisions within HHS that were searched for responsive documents;
- (d) an identification, by specific Bates ranges, of the individual employees, files, computers, and locations from which documents were collected; and
- (e) decisions to withhold any documents responsive to the subpoenas on "relevance" or "deliberative process" grounds, including an identification of the individual(s) who decided to withhold such documents and the reasons therefore.

24. The United States' initial production of documents pursuant to Rule 26(a)(1)(B) of the Federal Rules of Civil Procedure, including:

- (a) the policies, directives, instructions, and procedures and practices relating to the search for and collection of responsive documents; and
- (b) an identification, by specific Bates ranges, of the individuals and locations from which documents were collected.

25. The United States' responses to Defendant Abbott Laboratories, Inc.'s First Set of Requests for the Production of Documents and Tangible Things to Plaintiff United States of America, including:

- (a) an identification of the individual employees, files, computers, locations, and agencies within the United States that the United States believes may have responsive documents;
- (b) the steps taken to identify sources of responsive documents and search for and collect responsive documents as of the date of the deposition;
- (c) the policies, directives, instructions, and procedures and practices relating to the search for and collection of responsive documents;
- (d) an identification of the individual employees, files, computers, locations, and agencies within the United States that were searched for responsive documents prior to the date of the deposition;

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- (e) an identification of the individual employees, files, computers, locations, and agencies within the United States from which documents were collected prior to the date of the deposition; and
- (f) decisions to withhold any documents responsive to the subpoenas on “relevance” or “deliberative process” grounds, including an identification of the individual(s) who decided to withhold such documents and the reasons therefore as of the date of the deposition.

Plaintiffs' Allegations

26. All facts or information regarding specific knowledge on the part of CMS, its employees, agents, or carriers, of the cost of each drug that the Government contends is potentially still at issue in this case, the “spread” with respect to such drugs, and any “marketing” of this spread by Abbott.

27. All communications between the United States and Ven-A-Care concerning the United States' decision to intervene against Abbott in this matter, the United States' decision to unseal the docket with respect to allegations against Abbott, and Ven-A-Care's adoption of the United States' original complaint against Abbott.

Sincerely,

/s/ R. Christopher Cook

R. Christopher Cook

cc: James J. Breen, Esq.
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